Roche

Pharmaceuticals

2139 '03 APR 23 A9:14

03D-0060
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

U.S.A.

Basel, April 22, 2003
Comments regarding your Draft Guidance for Industry: "Part 11, Electronic Records; Electronic Signatures - Scope and Application" (03D-0060)

Dear Madam, Dear Sir,

Thank you for affording us the opportunity to comment on this draft guidance related to 21 CFR Part 11.

Your draft guidance document was internally distributed amongst a Roche expert group for electronic records and signatures for comments. This expert group has roughly 50 members from various countries. Please find enclosed the consolidated comments from our group.

1. *Lines 42-44 and 236-239 – Legacy Systems*
Current draft: ...systems that were operational before August 20, 1997, the effective date of Part 11 (commonly known as existing or legacy systems) while we are re-examining Part 11.
Suggested text: ...systems that were operational before August 20, 1997, the effective date of Part 11 (commonly known as existing or legacy systems) while we are re-examining Part 11. A legacy system will also be interpreted as including those systems having implemented bug fixes and Y2K patches (i.e., fixes to comply with year 2000 requirements) that were introduced after August 20, 1997.
Reason: There is still some old and very reliable process equipment operating in the industry that was built in the late eighties. It is often impossible to implement audit trail or access control levels in such old equipment, however some minor changes had to be instituted to ensure Y2K compliance.

2. *Lines 74-75*
Current draft: Guidance for industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps
Suggested text: - (nothing – this draft guidance does not need to be withdrawn)
Reason: This draft guidance (Guidance for industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps) provided valuable input. We could use it. It did not lead to any comments from Roche side.

03D-0060 C 6

F. Hoffmann-La Roche Ltd Pharmaceuticals Division CH-4070 Basel Global Quality Tel. +41-61-688 4608

3. *Line 182*
Current draft: (e.g., in a Standard Operating Procedure (SOP))
Suggested text: - (nothing – leave the bracket expression away)
Reason: Record classification sheets or record classification reports in the framework of validation or GxP assessments of systems should also be included and are believed to be more appropriate, because a Standard Operating Procedure usually describes "What you need to do as a user", whilst the other mentioned documents are more descriptive.

4. *Line 208*
Current draft: ...a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety and record integrity
Suggested text: ... traceability of all aspects of the product
Reason: Traceability is much more important than a risk assessment. The actual reason for every record to exist is to give traceable quality. For example if a tablet press is recording the compressing forces for each individual tablet this record can be destroyed when all the data is within the specified limits. The record was a pure process control record and is not attributable to the individual tablet when tablet compressing is finished.
If the documented risk assessment should be part of the final guidance, please indicate that such information could be included in other validation documentation.

5. *Lines 257-261*
Current draft: ...If you have the ability to search, sort, or trend Part 11 records, copies provided to the Agency should provide the same capability if it is technically feasible
Suggested text: ...If you have the ability to search, sort, or trend Part 11 records, copies provided to the Agency should provide the same capability if it is technically feasible, should not violate proprietary software licenses, and provided that the FDA official conducting the manipulation is trained in the use of the specific software, and that he/she follows the same procedure the company was using. In the case of differing results, the company shall be involved in the investigation of the error.
Reason: Software is sometimes protected by licenses. The results of trending may be incorrect or misleading if the training is not appropriate. Calculations that are performed in another way than according to the original procedure may also be incomplete or erroneous.

Please do not hesitate to contact us should you require further clarification.

Yours sincerely,

F. Hoffmann-La Roche Ltd

ppa P. Bosshard

ppa. W. Schumacher

Dr. Peter Bosshard
Quality Manager
Global Quality

Dr. Wolfgang Schumacher
Head of Informatics Quality
Global Informatics